



DOCKET NO.: C1040.70006US00

DW  
16328

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: McCluskie et al.  
Serial No.: 09/316,199  
Confirmation No.: 7506  
Filed: May 21, 1999  
For: METHODS AND PRODUCTS FOR INDUCING MUCOSAL IMMUNITY  
Examiner: Dave Trong Nguyen  
Art Unit: 1632

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 29<sup>th</sup> day of December, 2004.

Kristin J. Ketelhut  
Kristin J. Ketelhut

MAIL STOP AMENDMENT

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check in the amount of \$180 is enclosed to cover the filing fee. If the fee is insufficient, the balance may be charged to Deposit Account 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
*McCluskie et al.*, Applicant

By:

Maria A. Trevisan

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Docket No.: C1040.70006US00

Date: December 29, 2004

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DOCKET NO.: C1040.70006US00

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Kristin J. Kefelut  
Kristin J. Kefelut

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MAIL STOP AMENDMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed after a first Office Action after the filing of a request for continued examination, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

The fee of \$180 as set forth in 37 C.F.R. §1.17(p) is enclosed.

01/05/2005 AWONDAF1 00000002 09316199

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850706.1

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
*C1037.70013US01	10/831,778	April 23, 2004	Bratzler et al.
*C1037.70039US01	10/816,220	April 1, 2004	McCluskie et al.
*C1037.70050US01	10/952,254	September 27, 2004	Uhlmann et al.
*C1037.70054US01	10/973,927	October 25, 2004	Lipford et al.
*C1039.70020US01	10/921,086	August 18, 2004	Krieg et al.
*C1039.70035US01	10/884,866	July 2, 2004	Krieg et al.
*C1039.70035US02	10/888,803	July 9, 2004	Krieg et al.
*C1039.70048US03	10/831,647	April 23, 2004	Krieg et al.
*C1039.70048US04	10/847,642	May 15, 2004	Krieg et al.
*C1039.70048US05	10/877,407	June 24, 2004	Krieg et al.
*C1039.70048US06	10/884,852	July 2, 2004	Krieg et al.
*C1039.70048US07	10/888,785	July 9, 2004	Krieg et al.
*C1039.70048US08	10/888,449	July 9, 2004	Krieg et al.
*C1039.70048US09	10/894,657	July 16, 2004	Krieg et al.
*C1039.70048US10	10/894,862	July 16, 2004	Krieg et al.
*C1039.70048US11	10/928,762	August 26, 2004	Krieg et al.
*C1039.70048US12	10/956,745	October 1, 2004	Krieg et al.
*C1039.70048US13	10/956,494	October 1, 2004	Krieg et al.
*C1039.70048US14	10/972,301	October 22, 2004	Krieg et al.
*C1039.70048US15	10/987,146	November 12, 2004	Krieg et al.

\*a copy of this reference is not provided as the Office hereby waives the requirement under 37 CFR 1.98(a)(2)(iii) for submitting a copy of each cited U.S. patent application filed after June 30, 2003 and for applications filed before June 30, 2003, or that entered the national stage before June 30, 2003, if they are scanned to Image File Wrapper system and are available on Private PAIR.

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
*C1039.70057US01	10/838,659	May 3, 2004	Davis et al.
*C1039.70058US01	10/831,775	April 23, 2004	Davis et al.
*C1039.70083US08	10/847,650	May 15, 2004	Krieg et al.
*C1039.70083US09	10/888,885	July 9, 2004	Krieg et al.
*C1039.70083US10	10/888,089	July 9, 2004	Krieg et al.
*C1040.70006US01	10/888,886	July 9, 2004	McCluskie et al.
*C1040.70012US00	10/644,267	August 20, 2003	Davis et al.
*C1041.70002US01	10/877,369	June 25, 2004	Wagner et al.
*C1041.70002US02	10/876,965	June 25, 2004	Wagner et al.
*C1041.70002US03	10/876,892	June 25, 2004	Wagner et al.
*C1041.70005US01	10/811,226	March 26, 2004	Wagner et al.
*C1041.70005US02	10/894,655	July 16, 2004	Wagner et al.
C1041.70010US00	09/786,436	March 2, 2001	Wagner et al.
*C1041.70016US01	10/884,372	July 2, 2004	Bauer et al.
*C1041.70034US01	10/978,283	October 29, 2004	Uhlmann et al.
*C1041.70036US01	10/872,196	June 18, 2004	Lipford et al.
*C1041.70040US00	10/666,844	September 19, 2003	Lipford et al.
*C1041.70043US01	10/977,560	October 29, 2004	Jurk et al.

\*a copy of this reference is not provided as the Office hereby waives the requirement under 37 CFR 1.98(a)(2)(iii) for submitting a copy of each cited U.S. patent application filed after June 30, 2003 and for applications filed before June 30, 2003, or that entered the national stage before June 30, 2003, if they are scanned to Image File Wrapper system and are available on Private PAIR.

The Applicant would like to bring to the Examiner's attention the enclosed search report from a corresponding International or Foreign National Application.

<u>Docket No.</u>	<u>Serial No.</u>	<u>Mailing Date</u>	<u>Type of Communication(s)</u>
C1040.70006WO00	PCT/US99/11359	19 June 2000	International Preliminary Examination Report
C1040.70006WO00	PCT/US99/11359	28 December 1999	International Search Report

### PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

Conf. No.: 7506

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
*McCluskie et al., Applicant*

By:



Maria A. Trevisan, Reg. No. 48,207  
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600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

Docket No.: C1040.70006US00

Date: December 21, 2004

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <small>JAN 03 2005</small>				APPLICATION NO.: 09/316,199	ATTY. DOCKET NO.: C1040.70006US00
				FILING DATE: May 21, 1999	CONFIRMATION NO.: 7506
				APPLICANT: McCluskie et al.	
				GROUP ART UNIT: 1632	EXAMINER: Dave Trong Nguyen
Sheet	1	of	8		

**U.S. PATENT DOCUMENTS**

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
		4,452,775		Kent	06-05-1984
		4,544,559		Gil et al.	10-01-1985
		4,994,442		Gil et al.	02-19-1991
		5,066,500		Gil et al.	11-19-1991
		5,679,647		Carson, et al.	10-21-1997
		5,804,566		Carson et al.	09-08-1998
		5,830,877		Carson et al.	11-03-1998
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		2001-0046967	A1	Van Nest et al.	11-29-2001
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		2002-0198165	A1	Bratzler et al.	12-26-2002
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JAN 03 2005

U.S. PATENT AND TRADEMARK OFFICE

**INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

Sheet 2 of 8

APPLICATION NO.:	09/316,199	ATTY. DOCKET NO.:	C1040.70006US00
FILING DATE:	May 21, 1999	CONFIRMATION NO.:	7506
APPLICANT: McCluskie et al.			
GROUP ART UNIT:	1632	EXAMINER:	Dave Trong Nguyen

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
		2003-0087848	A1	Bratzler et al.	05-08-2003
		2003-0091599	A1	Davis et al.	05-15-2003
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		2003-0125292	A1	Semple et al.	07-03-2003
		2003-0130217	A1	Raz et al.	07-10-2003
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		2003-0138413	A1	Vicari et al.	07-24-2003
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		2003-0143213	A1	Raz et al.	07-31-2003
		2003-0148316	A1	Lipford et al.	08-07-2003
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		2003-0166001	A1	Lipford	09-04-2003
		2003-0176389	A1	Raz et al.	09-18-2003
		2003-0181406	A1	Schetter et al.	09-25-2003
		2003-0191079	A1	Krieg et al.	10-09-2003
		2003-0203861	A1	Carson et al.	10-30-2003
		2003-0212026	A1	Krieg et al.	11-13-2003
		2003-0212028	A1	Raz et al.	11-13-2003
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		2003-0232074	A1	Lipford et al.	12-18-2003
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		2004-0106568	A1	Krieg et al.	06-03-2004
		2004-0115219	A1	Ahn et al.	06-17-2004
		2004-0131628	A1	Bratzler et al.	07-08-2004

<p style="text-align: center;"><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p>				APPLICATION NO.: 09/316,199	ATTY. DOCKET NO.: C1040.70006US00
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				GROUP ART UNIT: 1632	EXAMINER: Dave Trong Nguyen
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Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
		2004-0132685	A1	Krieg et al.	07-08-2004
		2004-0142469	A1	Krieg et al.	07-22-2004
		2004-0143112	A1	Krieg et al.	07-22-2004
		2004-0147468	A1	Krieg et al.	07-29-2004
		2004-0152649	A1	Krieg	08-05-2004
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		2004-0162262	A1	Krieg et al.	08-19-2004
		2004-0167089	A1	Krieg et al.	08-26-2004
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		2004-0181045	A1	Krieg et al.	09-16-2004
		2004-0198688	A1	Krieg et al.	10-07-2004

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
		EP	1 187 629	A2	Smithkline Beecham Biologicals, S.A.	10-26-2000	
		WO	93/15207	A2	Viagene Inc.	08-05-1993	
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		WO	96/14074	A1	Regents of the University of California	05-17-1996	
		WO	97/12633	A1	Immunex Corporation	04-10-1997	
		WO	98/01538	A1	Immunex Corporation	01-15-1998	
		WO	98/52962	A1	Merck and Co., Inc.	11-26-1998	
		WO	98/55609	A1	Regents of the University of California	12-10-1998	
		WO	99/33868	A2	Smithkline Beecham Biologicals, S.A.	07-08-1999	
		WO	99/61056	A2	Loeb Health Research Institute at the Ottawa Hospital	12-02-1999	
		WO	00/09159	A1	Aquila Biopharmaceuticals, Inc.	02-24-2000	
		WO	00/15256	A2	Pasteur Merieux Serums Et Vaccins [FR]	03-23-2000	Abstract
		WO	00/23105	A2	Smithkline Beecham Biologicals, S.A.	04-27-2000	
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		WO	00/54803	A2	Panacea Pharmaceuticals, LLC.	09-21-2000	
		WO	00/56359	A2	Smithkline Beecham Biologicals, S.A.	09-28-2000	
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		WO	00/62800	A2	SmithKline Beecham Biologicals, S.A.	10-26-2000	
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		WO	01/00231	A2	SmithKline Beecham Biologicals, S.A.	01-04-2001	
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<b>FORM PTO-1449/A and B (Modified)</b> <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 09/316,199	ATTY. DOCKET NO.: C1040.70006US00
				FILING DATE: May 21, 1999	CONFIRMATION NO.: 7506
				APPLICANT: McCluskie et al.	
Sheet	4	of	8	GROUP ART UNIT: 1632	EXAMINER: Dave Trong Nguyen

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	WO	01/17550	A2	SmithKline Beecham Biologicals, S.A.	03-15-2001		
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	WO	03/094963	A2	INEX Pharmaceuticals Corp.	11-20-2003		
	WO	03/100040	A1	Merck Patent GMBH	12-04-2003		

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No.	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		ADEREM et al., Toll-like receptors in the induction of the innate immune response. Nature. 2000 Aug 17;406(6797):782-7.	
		ASKEW et al., CpG DNA induces maturation of dendritic cells with distinct effects on nascent and recycling MHC-II antigen-processing mechanisms. J Immunol. 2000 Dec 15;165(12):6889-95.	
		BAUER et al., DNA activates human immune cells through a CpG sequence-dependent manner. Immunology. 1999 Aug;97(4):699-705.	
		BROIDE et al., DNA-Based immunization for asthma. Int Arch Allergy Immunol. 1999 Feb-Apr;118(2-4):453-6.	
		BRUNNER et al., Enhanced dendritic cell maturation by TNF-alpha or cytidine-phosphate-guanosine DNA drives T cell activation in vitro and therapeutic anti-tumor immune responses in vivo. J Immunol. 2000 Dec 1;165(11):6278-86.	
		CALAROTA et al., Cellular cytotoxic response induced by DNA vaccination in HIV-1-infected patients. Lancet. 1998 May 2;351(9112):1320-5.	
		CARSON et al., Oligonucleotide adjuvants for T helper 1 (Th1)-specific vaccination. J Exp Med. 1997 Nov 17;186(10):1621-2.	

FORM PTO-1449/A and B (Modified) JAN 03 2005				APPLICATION NO.: 09/316,199	ATTY. DOCKET NO.: C1040.70006US00
				FILING DATE: May 21, 1999	CONFIRMATION NO.: 7506
				APPLICANT: McCluskie et al.	
Sheet	5	of	8	GROUP ART UNIT: 1632	EXAMINER: Dave Trong Nguyen

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
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FORM PTO-1449/A and B (Modif'd)

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FILING DATE: May 21, 1999

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet

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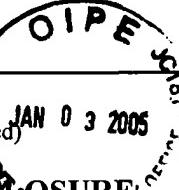
APPLICANT: McCluskie et al.

GROUP ART UNIT: 1632

EXAMINER: Dave Trong Nguyen

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

APPLICATION NO.:	09/316,199	ATTY. DOCKET NO.:	C1040.70006US00
FILING DATE:	May 21, 1999	CONFIRMATION NO.:	7506
APPLICANT:	McCluskie et al.		
GROUP ART UNIT:	1632	EXAMINER:	Dave Trong Nguyen

Sheet 7 of 8

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
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<b>FORM PTO-1449/A and B (Modified)</b> <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 09/316,199	ATTY. DOCKET NO.: C1040.70006US00
				FILING DATE: May 21, 1999	CONFIRMATION NO.: 7506
				APPLICANT: McCluskie et al.	
Sheet	8	of	8	GROUP ART UNIT: 1632	EXAMINER: Dave Trong Nguyen

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		WEIGEL et al., Comparative analysis of murine marrow-derived dendritic cells generated by Flt3L or GM-CSF/IL-4 and matured with immune stimulatory agents on the in vivo induction of antileukemia responses. Blood. 2002 Dec 1;100(12):4169-76. Epub 2002 Aug 08.	
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EXAMINER:	DATE CONSIDERED:
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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